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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,942

12/28/2006

Alec D. Lebsack

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EXAMINER

BERNHARDT, EMILY B

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,942	Applicant(s) LEBSACK ET AL.	
	Examiner EMILY BERNHARDT	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
 4a) Of the above claim(s) 10-15, 18, 19 and 23-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 17 and 20-22 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/13/06</u> . | 6) <input type="checkbox"/> Other: ____. |

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9,16-17 and 20-22, drawn to compounds of formula I where E & D are both N, compositions and first recited use.

Group II, claim(s) 1,2,4-8,17 and 20-22, drawn to compounds of formula I where one of E or D is O and other is N, compositions and 1st recited use.

Group III, claim(s) 1,10-15 and 20-22, drawn to compounds of formula II where E and D are both N, compositions and 1st recited use.

Group IV, claim(s) 1,10,12-14 and 20-22, drawn to compounds of formula II where one of E or D is O and the remaining one is N, compositions and 1st recited use.

Group V, claim(s) 18-19, drawn to complex compositions employing compounds of I-IV.

Group VI, claim(s) 20-37, drawn to additional uses employing compounds of I-IV.

If group V or VI is elected applicants must further select a compound group and a specific 2nd ingredient from among choices (i)- (xxxi) for group VI.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: They relate to compounds of considerable dissimilarity given the many choices permitted at variables A,B,D and E. As a result they do not belong to a recognized class of compounds and there exists no substantial structural feature in common that can be said to provide a *priori* an advance over the art. Note the "X" references cited in the search report.

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Where more than one use is claimed along with compounds, the first recited invention is considered to form part of the main invention. See 37 CFR 1.475(d). Group V lacks unity with remaining groups as it recites a variety of structurally unrelated compounds which are not art-recognized equivalents and thus would be expected to raise different issues of patentability within members of the group as well outside the group.

During a telephone conversation with Ms. Ayler on 12/9/08 a provisional election was made with right of traverse to prosecute the invention of I, claims 1-9,16,17 and 20-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-15,18-19 and 23-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

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All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 1-9,17 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. It is not seen how A or B can be O given the bonding these variables require.
2. In the "F" definition its not clear what is being claimed- heteroaryl or pyridyl.

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3. In the "G" definition if an H of the methylene is replaced by a C=O the resulting moiety would be open-ended as carbonyl is divalent. Also an "is" should follow "methylene".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6,7,17 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chambers (WO'305) and citing Blackaby as evidence of what Chambers teaches. The WO publication describes at least 2 compounds within the instant scope for enhancing cognition based on compounds' ability to bind to GABA_A receptors. See egs. 31 and 37 on p.79. While the reference does not teach treating pain, Blackaby is applied to show that compounds that bind to the GABA_A receptors are implicated for treating pain. See page 1, right column. Extrinsic evidence is permitted to be considered in anticipations for explaining (or evidencing) what the meaning of the reference would have meant to those skilled in the art at the time the invention was made. Note for example, Ciba-Geigy v Alza 37 USPQ 2d 1337. Thus, while Chambers does not mention the claimed uses, following the teachings of Chambers one would be administering to a host an instant drug that targets said receptors and thus inherently performs the same function as claimed herein to treat diseases described in the art and particularly recited herein. See Ex parte Novitski 26 USPQ 2d 1389 as well as the more recent decision, Integra LifeSciences v. Merck 50 USPQ 2d 1846.

Claims 20-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating various types of pain, does not reasonably provide enablement for its prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Compounds that possess analgesic activity are known to treat pain not prevent its initial onset. As far as the examiner is aware there are no current GABA agonists/ antagonists that are known for use as a preventive remedy.

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Lesback cited by applicants is not a competent reference as applicants' provisional priority provides support for subject matter claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Bernhardt/
Primary Examiner, Art Unit
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